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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,981	12/16/2005	Thomas Kaup	8932-988-999	5254

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EXAMINER

WOODALL, NICHOLAS W

ART UNIT	PAPER NUMBER
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3733

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/529,981

Applicant(s)

KAUP ET AL.

Examiner

Nicholas Woodall

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 9-12, 14-18, 20, 22 and 23 is/are rejected.
- 7) ☒ Claim(s) 6-8, 13, 19 and 21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 March 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to applicant's amendment received on 11/30/2006.

Allowable Subject Matter

2. The indicated allowability of claims 3 and 4 is withdrawn in view of the newly discovered reference(s) to Shannon (U.S. Publication 2005/0113909). Rejections based on the newly cited reference(s) follow.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the expansion agent including a threaded connection between the first sheath and the expansion agent and the device includes a second bone fixation implant as stated in claims 21 and 22 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheets should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the

renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 15 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
6. Claim 15 recites the limitation "the second sheath" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1, 2, 4, 10-12, 16, 17, 20, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lawes (U.S. Patent 5,454,813) in view of Hardinge (U.S. Patent 2,381,050).

Regarding claim 1, Lawes discloses a device comprising an intramedullary pin and a bone fixation implant. The intramedullary pin includes a longitudinal axis and at least one transverse borehole defining a central borehole axis, wherein the central borehole axis forms a non-zero angle with respect to the longitudinal axis of the pin. The bone fixation implant includes a front end, a rear end, and a shaft. Regarding claim 11, Lawes discloses a device further comprising a rotation safeguard to prevent the rotation of the bone fixation implant relative to the intramedullary pin about the central borehole axis. Lawes fails to disclose the bone fixation element including an expandable sheath at the front end of the bone fixation implant (claim 1) and an expansion agent (claim 16). Hardinge teaches a device comprising a bone fixation implant that includes a stainless steel (claim 4) expandable sheath with external threads (claim 12) at the front end of the bone fixation implant and an expansion agent that is conically tapered toward the rear end of the implant (claim 17) and includes a threaded connection with the shaft (claim 20) in order to forcibly draw together adjacent bone fragments (column 1 lines 45-50) and to radially expand the split ends of the sheath (column 3 lines 15-27). It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device of Lawes with a bone fixation implant further including an expandable sheath and an expansion agent in view of Hardinge in order to forcibly draw together adjacent bone fragments and to radially expand the split ends of the sheath.

Regarding claim 22, the combination of Lawes and Hardinge disclose the invention as claimed except for the device further comprising a second bone fixation element. It would have been obvious to one having ordinary skill in the art at the time

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the invention was made to manufacture the device of Lawes modified by Hardinge with a second bone fixation device, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

9. Claims 3, 5, 9, 14, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lawes (U.S. Patent 5,454,813) in view of Hardinge (U.S. Patent 2,381,050) further in view of Shannon (U.S. Publication 2005/0113909).

Regarding claims 3, 14, and 23, the combination of Lawes and Hardinge disclose the invention as claimed except for the bone fixation implant further comprising a second expandable sheath disposed on the first expandable sheath. Shannon teaches gluing polymer coatings to the external surface of expandable implants in order to make the implants more biocompatible (page 3 paragraph 025). The polymer coating would create an expandable second sheath disposed on the first sheath coaxially with the central borehole axis. It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device of Lawes modified by Hardinge with a bone fixation implant further including a polymer coating glued to the first expandable sheath in view of Shannon in order to make the implant more biocompatible.

Allowable Subject Matter

10. Claims 6-8, 13, 19, and 21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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11. Claim 15 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Response to Arguments

12. Applicant's arguments with respect to claims 1, 2, and 23 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 for cited references the examiner felt were relevant to the application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicholas Woodall whose telephone number is 571-272-5204. The examiner can normally be reached on Monday to Friday 8:00 to 5:30 EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NWW



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER